

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000054447	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2004/003689	International filing date (day/month/year) 07.04.2004	Priority date (day/month/year) 11.04.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant BASF AKTIENGESELLSCHAFT		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-12 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-11 _____ received by this Authority on 11.12.2004 with letter
- nos.* _____ received by this Authority on of 30.09.2004
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-11	NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
1. This report makes reference to the following documents:			
D1: EP-A-1 048 668 (HOFFMANN LA ROCHE) 2 November 2000 (2000-11-02)			
D2: EP-A-0 995 749 (HOFFMANN LA ROCHE) 26 April 2000 (2000-04-26)			
D3: EP-A-0 730 034 (HOFFMANN LA ROCHE) 4 September 1996 (1996-09-04)			
D4: EP-A-0 457 075 (BASF AG) 21 November 1991 (1991-11-21)			
D5: EP-A-0 307 767 (HOFFMANN LA ROCHE) 22 March 1989 (1989-03-22)			
With the letter of 30 September 2004, the applicant submitted a new set of claims, claims 1-11, from which the originally submitted claims 12-17 were deleted and in which claim 1 was amended by the inclusion of the subject matter of the original claim 3. The requirements of PCT Article 19 have been met.			

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2.

2.1 Novelty*Claims 1-11*

The subject matter of claims 1-11 differs from

- D1 (see example 1 and claim 1), D2 (see example 1 and claim 1) and D3 (see example 1) by a precipitation directly after the dissolution process without the addition of active charcoal (see method step b) in claim 1)
- D4 by method step a)
- D5 by avoiding the use of a second solvent

Claims 1-11 meet the requirements for novelty.

3.2 Inventive step

D1 is regarded as the closest prior art. D1 discloses a method for producing riboflavin of modification B/C in granulated form (see example 1) characterized in that

- riboflavin of modification A is dissolved in aqueous inorganic acid
- the solvent is treated with activate carbon and subsequently filtered.

Proceeding from D1, the applicant describes the problem to be solved as that of providing a method for producing riboflavin of B/C modification in granulated form with a **high degree of purity** and a **high yield**.

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The solution to this problem is provided by a method according to claim 1 characterized by precipitation directly after the dissolution process, without the addition of active charcoal (method step b).

The problem cannot, however, currently be regarded as solved, because the application contains no reference to the degree of purity or yield of the B/C riboflavin produced using the method according to the application as compared to that produced using the method in the prior art.

Proceeding from the technical teaching of D1 and D2, a person skilled in the art is not surprised to obtain riboflavin of B/C modification in granulated form, even when active charcoal is not used. Paragraphs (0017) and (0033) of D1 teach that the B/C modification is no longer converted into A. Paragraph (0014) of D2 teaches that the active charcoal serves only to filter the dissolved impurities and therefore does not contribute to forming the B/C modification. Therefore, a person skilled in the art would not be surprised to obtain the riboflavin granulate of B/C modification according to the claimed method.

The presence of a surprising effect could

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substantiate an inventive step. The data in Table 3 of the present specification, however, do not substantiate an effect that would be considered surprising, since it is not clear whether the comparative tests were designed in accordance with the closest prior art, i.e. in accordance with example 1 in D1 and D2.

The requirements for inventive step are not currently fulfilled.